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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,538	09/29/2003	Bernard S. Green	26883	7499

7590 11/22/2006

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,538	GREEN ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group IV in the reply filed on 09/15/2006 is acknowledged. The claims that read on this group are 1-7 and 13-14, 13 was included because 14 depends upon it. The examiner suggests that the applicants should amend the claims in the next response so that they only read on the elected invention that is a method for treating gatroesophageal reflux disease, the method comprising administering a molecularly imprinted polymer.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants claim a method for treating a subject for gatroesophageal reflux disease (GERD), the method comprising administering a molecularly imprinted polymer (MIP). Applicants have failed to describe the polymers used in the specification that would show possession of the broad term "molecularly imprinted polymer" in the claims. In the experimental section the three polymers disclosed were formed from monomers of DEVPA (N,N'-diethyl(4-vinylphenyl)

amidine), methyl methacrylate and ethylene glycol dimethacrylate prepared in the presence of a bile acid salt, therefore applicants only have written description for an MIP formed from the above monomers with a bile acid salt as the template molecule. The experimental section in the specification describes three polymers (P1-P3) that were prepared using bile acid salts and capable of sequestering those bile salts, however the polymers only sequestered the specific bile salts GDCA, CDCA and LCA, there is inadequate written description to claim broadly any MIP that sequesters all toxins in general or all known bile acid salts from the disclosure. It is suggested by the examiner that applicants bring in the specific monomers DEVPA (N,N'-diethyl(4-vinylphenyl) amidine), methyl methacrylate and ethylene glycol dimethacrylate as well as the exact bile acid salts used as the template molecule which were GDCA, CDCA and LCA as a product by process limitation to define the exact type of MIP that applicants invented into claims 1 and 13 and cancel claims 3-4 and 5-6.

Claims 1-7 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of gatroesophageal reflux disease by orally administering a molecularly imprintable polymer formed from monomers of DEVPA (N,N'-diethyl(4-vinylphenyl)amidine) methyl methacrylate and ethylene glycol dimethacrylate prepared in the presence of a bile acid salt that sequesters the specific bile acids or salts selected from GDCA,CDCA and LCA, does not reasonably provide enablement for treatment of gatroesophageal reflux disease by orally administering any molecularly imprintable polymer. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a treatment of gatroesophageal reflux disease by orally administering any molecularly imprintable polymer. The instant specification fails to provide information that would allow the skilled artisan to practice the prevention of the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 1 is drawn to "a method for treating a subject for gatroesophageal reflux diseases (GERD from hereon) the method comprising: orally administering a molecularly imprinted polymer (MIP form hereon) to the subject."

(2) The breadth of the claims:

Claim 1 embraces a therapeutic MIP for GERD. This reads on the treatment or prevention of GERD by administration of any MIP. The specification only enables the

treatment of GERD with a molecularly imprintable polymer formed from monomers of DEVPA (N,N'-diethyl(4-vinylphenyl)amidine) methyl methacrylate and ethylene glycol dimethacrylate prepared in the presence of a bile acid salt that sequesters the specific bile acids or salts selected from GDCA,CDCA and LCA.

(3) The state of the prior art:

The state of the art regarding treating GERD is high. However, the state of the art for treating GERD with any type of MIP does not exist.

(4) The predictability or unpredictability of the art:

The predictability for treating GERD with any type of MIP is also non-existent. Therefore, to one skilled in the art, treating GERD with any type of MIP is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the treating GERD with any type of MIP is completely lacking. The specification as filed does not speak on or show any working examples or any studies for treating GERD with any type of MIP. The specification only enables treatment of GERD with a molecularly imprintable

polymer formed from monomers of DEVPA (N,N'-diethyl(4-vinylphenyl)amidine) methyl methacrylate and ethylene glycol dimethacrylate prepared in the presence of a bile acid salt that sequesters the specific bile acids or salts selected from GDCA,CDCA and LCA. The specification does not teach how to treat GERD with any type of MIP. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2194.

(7) The quantity of experimentation necessary:

The instant claims read on treating GERD with any type of MIP. As discussed above the specification fails to provide any support for treating GERD with any type of MIP. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the specification is enabled for treatment of GERD with a molecularly imprintable polymer formed from monomers of DEVPA (N,N'-diethyl(4-vinylphenyl)amidine) methyl methacrylate and ethylene glycol dimethacrylate prepared in the presence of a bile acid salt that sequesters the specific bile acids or salts selected from GDCA,CDCA and LCA, but is not enabled for treating GERD with any type of MIP.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER